



## Express Mail No. EV 687 636 766 US

## INFORMATION DISCLOSURE STATEMENT

Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Attorney Docket	INTM-018
First Named Inventor	HSU, HENRY H.
Application Number	10/526,087
Confirmation No.	6478
Filing Date	September 14, 2005
Group Art Unit	1646
Examiner Name	
Title: "COMBINATION	ON THERAPY FOR TREATMENT OF

FIBROTIC DISORDERS"

Sir:

This is an Information Disclosure Statement submitted for the Examiner's consideration. A Form PTO-SB/08A listing the references and copies of the cited references accompany this paper. Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record.

This Information Disclosure Statement is not intended as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one of the above references constitutes prior art to the present application within the meaning of 35 U.S.C.§102.

As applicants have not yet received a first Action on the merits, no fee is believed to be required for filing this Disclosure Statement. If, however, the PTO finds that for some reason a fee is due, our Deposit Account No. 50-0815, Order No. INTM-018 may be charged thereon.

By:

Date: Feb. 13, 2006

BOZICEVIC, FIELD & FRANCIS LLP 1900 University Avenue, Suite 200 East Palo Alto, California 94303 Telephone: (650) 327-3400

Facsimile: (650) 327-3231

Respectfully submitted, BOZICEVIC, FIELD & FRANCIS LLP

Paula A. Borden

Registration No. 42,344

FEB 13 2006

PTO/SB/08a (08-03) Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

red to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known 10/526,087 **Application Number** September 14, 2005 Filing Date First Named Inventor HSU, HENRY H. Art Unit 1646 To Be Assigned **Examiner Name** 

(use as many sheets as necessary) Sheet 4 Attorney Docket Number INTM-018

			U.S. PATENT D	OCUMENTS	
Examiner Initials'	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
- · · -		<b>US-</b> 6,294,350	09-25-2001	Peterson	
		US- 5,310,562	05-10-1994	Margolin	
		<b>US-</b> 5,518,729	05-21-1996	Margolin	
		US- 5,716,632	02-10-1998	Margolin	
		US- 6,090,822	07-18-2000	Margolin	
		US- 5,474,981	12-12-1995	Leder et al.	
		US- 5,871,723	12-16-1999	Strieter et al.	
		US- 5,728,377	03-17-1998	Sarris et al.	
		US- 5,935,567	08-10-1999	Leder et al.	
		<b>US-</b> 5,994,292	11-30-1999	Tosato et al.	
		US- 6,491,906	12-10-2002	Strieter et al.	
		US- 5,145,677	09-08-1992	von Eichborn , et al.	
		<b>US-</b> 5,362,490	11-08-1994	Kurimoto et al.	
		US- 6,153,600	11-28-2000	Leder et al.	
		US-			
		US-			
		US-			

		FOREIG	N PATENT DO	CUMENTS		
		Foreign Patent Document			Pages, Columns, Lines, Where Relevant	
Examiner Initials'	Cite No. <sup>1</sup>	Country Code <sup>3</sup> –Number <sup>4</sup> –Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Passages or Relevant Figures Appear	T <sup>6</sup>
		WO 01/34180	05-17-2001	Lutz-Henning Block		
		EP 795,332	09-17-1997	Lutz-Henning Block		
		WO 01/62274	08-30-2001	Instituto Cientifico Y Tecnologico De Navarra, S.A.		
		WO 99/46392	09-16-1999	The Gov't of the USA represented by The Secretary Department of Health and Human Services		
		EP 0328255		Baker Cummins Pharmaceuticals, inc.		
		W0 01/23006	04-05-2001	Amarillo Biosciences, Inc.		

Examiner	Date		
Signature	Considered		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant, 1 Applicant's unique citation designation number (optional), 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Papework Reduction Act of 1995 to persons are required to respond to a collection of information unless it contains a valid OMB control number.

FEB 13 2006

Complete if Known Substitute for form 1449B/PTO Application Number 10/526,087 Filing Date September 14, 2005 INFORMATION DISCLOSURE HSU, HENRY H. First Named Inventor STATEMENT BY APPLICANT Art Unit 1646 **Examiner Name** To Be Assigned (use as many sheets as necessary) INTM-018 4 Attorney Docket Number Sheet

	0	NON PATENT LITERATURE DOCUMENTS	_
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Ziesche et al. (1999) N. Engl. J. Med. 341:1264-1269	
		du Bois (1999) N. Engl. J. Med. 341:1302-1304	
		King (2000) N. Engl. J. Med. 342:974-975	
		Ziesche and Block (2000) Wien. Klin Wochenschr. 112:785-790;	<del> </del>
		Raghu et al. (1999) Am. J. Respir. Crit. Care Med. 159:1061-1069	
		Stern et al. (2001) Chest 120:213-219;	
		Gay et al. (1998) Am. J. Respir. Crit. Care Med. 157:1063-1072	<del>                                     </del>
		Dayton et al. (1993) Chest 103:69-73	$\vdash$
		Al-Bayati et al. (2002) Biochem. Pharmacol. 64:517-525	<del> </del>
		Shihab et al. (2002) Am. J. Transplant. 2:111-119	
Examiner		Date	<u></u>

Examiner Date Considered			
Considered	Examiner	Date	
Ognature	Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO**: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	PADEMAN				Complete if Known	
Substitute	e for form 1449B/PTO			Application Number	10/526,087	
	INFORMATION DISCL	OSI	IRF	Filing Date	September 14, 2005	
į	STATEMENT BY APP			First Named Inventor	HSU, HENRY H.	
	0171121112111 21 711 1			Art Unit	1646	
	(use as many sheets as ne	cessa	(ער	Examiner Name	To Be Assigned	
Sheet	3	of	4	Attorney Docket Number	INTM-018	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		Yu et al. (2002) Curr. Opinion Pharmacol. 2:177-181	
		METAVIR (1994) Hepatology 20:15-20	
		Brunt (2000) Hepatol. 31:241-246	
		Alpini (1997) J. Hepatol. 27:371-380	
		Baroni et al. (1996) <i>Hepatol</i> . 23 :1189-1199	<del> </del>
		Czaja et al. (1989) <i>Hepatol</i> . 10:795-800	
		Grossman et al. (1998) J. Gastroenterol. Hepatol. 13:1058-1060	-
		Rockey and Chung (1994) J. Invest. Med. 42:660-670	<u> </u>
		Sakaida et al. (1998) <i>J. Hepatol.</i> 28 :471-479	
		Shi et al. (1997) Proc. Natl. Acad. Sci. USA 94:10663-10668	-
		<u> </u>	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner

Signature

Date

Considered

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (08-03)

Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act 95, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

1				Complete if Known			
Substitute	e for form 1449B/PTO			Application Number	10/526,087		
l	INFORMATION DISCL	OS	URE	Filing Date	September 14, 2005		
STATEMENT BY APPLICANT				First Named Inventor	HSU, HENRY H.		
l	• • • • • • • • • • • • • • • • • • •			Art Unit	1646		
i	(use as many sheets as ne	cessa	ry)	Examiner Name	To Be Assigned		
Sheet	4	of	4	Attorney Docket Number	INTM-018		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
		Baroni et al. (1999) Liver 19:212-219	
	<u> </u>	Lortat-Jacob et al. (1997) J. Hepatol. 26:894-903	
		Llorent et al. (1996) <i>J. Hepatol.</i> 24:555-563	
		Luster and Leder (1996) <i>J. Exp. Med.</i> 178:1057-1065;	
		Tannenbaum et al. (1998) <i>J. Immunol.</i> 161:927-932	
		Narvaiza et al. (2000) J. Immunol. 164:3112-3122	
		Du X Weng H Cai W: "Histological changes in 20 hepatic fibrosis patients with chronic hepatitis B after recombinant human interferon gamma treatment" Medline, October 2001	
Examiner Signature		Date Considered	_

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.